



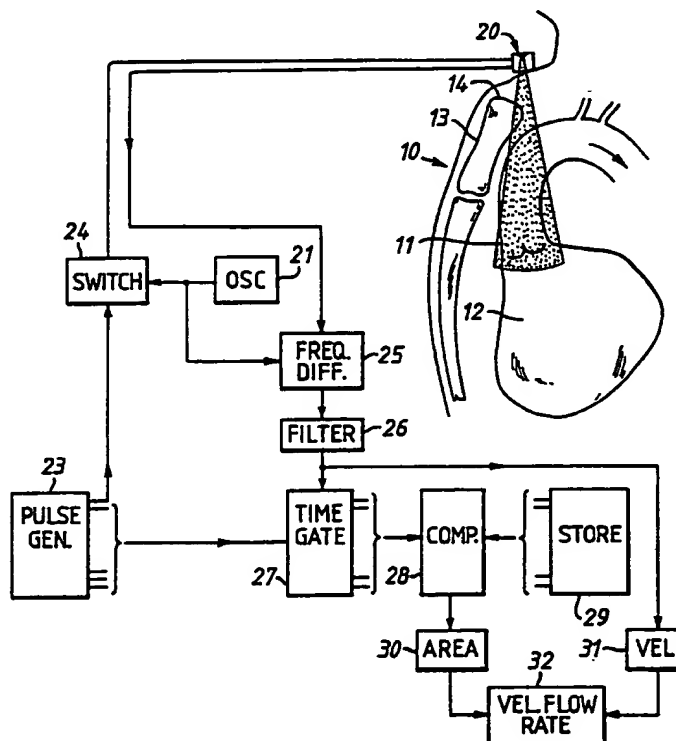
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61B 8/08, 8/06, G01B 17/00</b>		A1	(11) International Publication Number: <b>WO 92/22248</b>
			(43) International Publication Date: 23 December 1992 (23.12.92)
(21) International Application Number: PCT/GB92/01061 (22) International Filing Date: 12 June 1992 (12.06.92) (30) Priority data: 9112854.6                      14 June 1991 (14.06.91)                      GB (71) Applicant (for all designated States except US): BRITISH TECHNOLOGY GROUP LTD. [GB/GB]; 101 Newington Causeway, London SE1 6BU (GB). (72) Inventor; and (75) Inventor/Applicant (for US only) : SKIDMORE, Robert [GB/GB]; 2 Croft Close, Bitton, Bristol BS15 6HF (GB). (74) Agent: PARKER, Geoffrey; Patents Department, British Technology Group Ltd., 101 Newington Causeway, London SE1 6BU (GB).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent), US.  Published With international search report.	

## (54) Title: FLOWMETERS

## (57) Abstract

A method and apparatus for measuring the cross-sectional area of blood vessels, particularly the ascending aorta, is provided. An ultrasound probe (20) producing a divergent beam is directed downwardly via the suprasternal notch (14) and Doppler signals from the moving blood in the aorta (11) are detected. Signal processing means determine the Doppler power at successive ranges and the resulting power curve is correlated against stored curves representing a range of known aorta cross-sectional areas to find the closest fit. The velocity is also measured from the Doppler signal and hence the cardiac output can be determined.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	MI	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark	MG	Madagascar		
ES	Spain				

- 1 -

FLOWMETERS

This invention concerns flowmeters and more particularly flowmeters of Doppler ultrasound form.

5 Flowmeters of this last form are routinely used in medical practice for the purposes of blood flow measurement. These meters are usually designed for transcutaneous application, but some have been developed for catheterised application into a blood vessel of interest. However, such meters are often limited  
10 to the provision of measures only of blood velocity, and commonly so in the case of catheter flowmeters, whereas the medical community frequently has an interest in knowing the blood volume flow rate in the relevant vessel. This interest extends particularly to the case in which the vessel is the aorta because  
15 the rate is then an effectively direct indication of cardiac power output. In any event, although blood velocity may be measured without undue difficulty and blood volume flow rate is provided simply as the product of velocity and vessel cross-sectional area, an indication of the area in question is  
20 not readily attained. Indeed in the case of the interest in cardiac output, area is often estimated for a given patient by way of a quite separate imaging procedure.

An object of the present invention is to improve this situation and to this end there is provided a method for  
25 measuring the cross-sectional area of a conduit through which fluid is flowing, which method comprises projecting a diverging ultrasound beam along the conduit and detecting the resulting Doppler signals from a plurality of successive ranges including one where the beam has diverged at least to the boundary of the  
30 conduit, producing for said ranges respective representations of the power of the associated Doppler signals and providing a representation of the cross-sectional area of the conduit by comparison of said power representations with predetermined data.

Clearly the conduit can be a blood vessel and, more  
35 particularly, the aorta and, in this particular case, the beam is

- 2 -

conveniently directed transcutaneously by way of the suprasternal notch to pass longitudinally down the ascending aorta.

In a preferred form, the presently proposed method also entails determination of a measurement of the fluid flow velocity  
5 in the conduit by way of the Doppler signals, and preferably by reference to such signals at a range from the beam origin at least that of said one range.

The invention also provides, in another aspect from the presently proposed method, apparatus for carrying out such a  
10 method.

In order to clarify the invention as so far expressed, the same will now be described, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 schematically illustrates one form of the invention;  
15 Figure 2 graphically illustrates in an idealised manner the operational basis for the invention;

Figure 3 diagrammatically illustrates a form of a detail of the invention; and

Figure 4 illustrates an alternative form of a detail of the  
20 invention.

In Figure 1 the invention is illustrated for use relative to a patient's body denoted in part at 10, with the aorta, heart, sternum and suprasternal notch indicated respectively at 11-14 within the body.

25 Apparatus according to the invention in Figure 1 comprises an ultrasound transducer 20 operable in a transmission mode in response to an oscillator 21 to project a divergent beam 22 into the body 10. When the transducer is suitably located, the beam passes through the body tissue above the suprasternal notch and  
30 then longitudinally down the ascending aorta until the beam divergence is such that, at one range along the beam path, all of the blood flow through the aorta is isonated. Thereafter the beam diverges increasingly into the body tissue around the aorta.

This transmission operation is conducted in a pulsed manner  
35 under the control of an output from a pulse generator 23 which

- 3 -

opens and closes switch 24 between the oscillator and transducer.

The transducer is also operable between transmission pulses in a receiver mode to detect returning signals which return along the beam path. The resultant output signal from the transducer is subject to three operations which are conducted serially in any suitable sequence. As shown in the example of Figure 1 the signal is first applied, together with the output from oscillator 21, to a frequency difference circuit 25 to provide an output signal representing only Doppler components of the returning signals, that is to say, signals from surfaces which are moving relative to the transducer. These components will be predominantly from the blood corpuscles moving through the aorta, but some can arise from tissue surfaces moving due to respiratory or cardiac functions. These last components will be of a significantly lesser difference frequency than those due to blood flow and, as a second operation, are removed by way of an appropriate filter 26. Thirdly, the Doppler signal is time-gated at 27, under the control of a sequence of further pulse outputs produced by generator 23 between each successive pair of transducer transmission pulses, to present a series of signals representing the Doppler signals from successive ranges along the beam path. Particular variations of the signal processing system will not be described here in detail as such systems have been developed for use in Doppler ultrasound techniques and are generally well known. For example, a multigate system may be used to obtain information at the different ranges along the beam simultaneously, for example using parallel signal processing or using a serial digital signal processing system. Details of such systems are described in 'Doppler Ultrasound - Physics, Instrumentation and Clinical Applications' by D.H. Evans, W.N. McDicken, R. Skidmore and J.P. Woodcock (John Wiley & Sons 1989).

In the result signals are produced representing the Doppler signal power characteristic of the beam due to blood flow at a succession of ranges along the beam path.

- 4 -

This characteristic is compared, by way of a correlator 28, say, with similar characteristic representations of predetermined form associated with specific aortic cross-sectional areas and held in a store 29. The comparator provides at 30 a signal  
5 representing the area of the characteristic in the store best matched by that from the transducer.

In a separate operation the final time-gated output, or at least that at the one or subsequent range at which the blood flow is wholly isonated, is applied to a circuit 31 of a form to  
10 provide a signal representative of the mean blood velocity through the aorta.

This last velocity signal is combined with that representing cross-sectional area in a multiplier 32 to indicate cardiac output.

15 It may be required to determine the maximum blood flow in the ascending aorta in order to give a measurement of cardiac output at peak systole. This can be done by using the velocity signal to indicate the moment in time when a maximum velocity has been reached over the cardiac cycle, and automatically obtaining the  
20 signal representing cross-sectional area at that moment. Since the aortic diameter varies over the cardiac cycle this will represent an area larger than the mean cross-sectional area of the vessel. Multiplying the peak velocity measurement with this cross-sectional area measurement will thereby give a  
25 representation of peak systolic cardiac output. Variations in the individual measurements made at this point in the cycle can be allowed for by systolic coherent averaging, in which signals are averaged over, say, 10 heart-beats at systole.

The provision of the velocity signal can be effected in  
30 circuit 31 in known manner, but the basis for cross-sectional area determination requires clarification and this is given with reference to Figure 2.

Figure 2 graphically illustrates in an idealised manner four different situations for a given beam passing from the skin S  
35 through tissue of thickness  $T_1$  or  $T_2$  into an aorta of diameter  $D_A$

- 5 -

or  $D_B$  and the resultant Doppler signal power characteristics due to blood flow.

A general point to note for each situation is that there is no Doppler blood signal, but there will be some beam attenuation, while the beam passes through the tissue. Accordingly each characteristic commences with a declining portion distinctively indicated in broken line form. This portion will of course occur for a period dependent on the tissue thickness and this is denoted as time  $t_1$  and  $t_2$  respectively for thicknesses  $T_1$  and  $T_2$  relative to a transmission pulse occurring at time  $t_0$ .

Doppler blood signals are initiated when the beam enters the aorta and this is indicated by presentation of the related power characteristic in solid line form. Also the characteristic continues to decline due to attenuation, but at a reduced rate as the attenuation in blood is less than that in tissue.

The beam is of course diverging and a point is reached, namely the one range referred to above, at which the whole of the cross section of the aorta is isonated and the beam thereafter passes increasingly through tissue again. This gives rise to a markedly discontinuous downturn in the characteristic because, although the aorta is still wholly isonated, a progressively decreasing proportion of the beam power is involved. In any event this discontinuity will occur at a time and range which depends on the cross-sectional diameter and this is denoted at times  $t_3$  and  $t_4$  respectively for diameters  $D_A$  and  $D_B$ .

In the result it will be seen that each different situation gives rise to a uniquely related characteristic such as  $T_1 D_A$  to  $T_2 D_B$  and, even though idealised in a simple manner, this holds in reality sufficient for the present purpose. Thus, it is possible to compare an actual characteristic with predetermined forms and thereby determine the diameter, or cross-sectional area, the two being essentially synonymous, as it were, assuming circular cross section. The comparison with predetermined data is preferably carried out after normalising the obtained power characteristic, for example the normalisation is such that the initial signal

- 6 -

value when the beam enters the aorta (at point  $t_1$  or  $t_2$  in Figure 2) is set at a nominal value of 1.0. Correlation means then use the predetermined data to ascertain the probability that the actual characteristic was obtained from a vessel with one of a finite range of cross-sectional areas, and the cross-sectional area selected is that corresponding to the highest probability. This does not require an impracticable storage requirement for the predetermined forms as the aortic diameter can sensibly be viewed as having a finite range extending over about 13 mm between minimum and maximum, and an accuracy of no less than 1 mm is clinically adequate.

Figure 3 diagrammatically illustrates a preferred transducer arrangement suitable for use with the present invention.

As is evident from the above discussion the invention rests on the provision of a divergent beam. This can lead to complexity in that, conventionally, this would be seen to require a convexly shaped transducer or a flat disc transducer in association with an appropriate lens. Moreover, with such arrangements, separate measures will be needed in respect of providing operational modes for transmission and reception.

As indicated in Figure 3, it is proposed that the transducer 40 be of composite flat form with a central disc 41 and a surrounding annulus 42. This transducer is operated by way of a transformer which, from a transmission point of view, has a primary winding 43 and two secondary windings 44, 45, the secondary windings being oppositely wound with that, 44, wound in common with the primary being connected with central disc 41, and the other secondary winding being connected with the surrounding annulus 42. The same transformer arrangement also serves for reception.

An alternative transducer arrangement is illustrated diagrammatically in Figure 4. This employs a single piezoelectric element 50 mounted within a housing 51 adjacent to an aperture 52 in the end wall of the housing. The housing is preferably of cylindrical form, fabricated from metal, such as



- 7 -

brass. The piezoelectric element is fixedly mounted in place by epoxy resin 53 and the housing may also contain a volume of damping material 54. The shape of the transmission field depends on the size of the aperture 52, a wider divergent field being  
5 produced as the aperture diameter is reduced. The transmission field is represented diagrammatically at 55.

- 8 -

CLAIMS

1. A method for measuring the cross-sectional area of a conduit through which fluid is flowing, which method comprises projecting a diverging ultrasound beam along the conduit and detecting the  
5 resulting Doppler signals from a plurality of successive ranges including one where the beam has diverged at least to the boundary of the conduit, producing for said ranges respective representations of the power of the associated Doppler signals, and providing a representation of the cross-sectional area of the  
10 conduit by comparison of said power representations with predetermined data.
2. A method according to Claim 1 in which the conduit is a blood vessel.
3. A method according to Claim 2 in which the beam is directed  
15 transcutaneously.
4. A method according to Claim 3 in which the conduit is the ascending aorta and the beam is directed by way of the suprasternal notch.
5. A method according to any preceding claim in which said power  
20 representations are normalised with respect to a reference datum and correlated against power representations of a similar form representing said predetermined data.
6. A method according to any preceding claim in which a  
measurement of the fluid flow velocity in the conduit is made  
25 from the Doppler signals from said one range where the beam has diverged at least to the boundary of the conduit.
7. A method according to Claim 6 in which the fluid flow velocity measurement is multiplied by the cross-sectional area as measured to determined fluid volume flow.
- 30 8. A method according to Claim 6 or 7 in which the fluid flow velocity measurement is used to determine a moment of peak flow within the conduit and the measurement of cross-sectional area is obtained at this same moment.
9. Apparatus for carrying out measurement of the cross-sectional  
35 area of a conduit through which fluid is flowing comprising:

- 9 -

an ultrasound transducer operable in a transmission mode to project a divergent beam along the conduit;

a receiver to detect returning signals;

5 signal processing means for producing a representation of the Doppler signal power characteristic of the beam due to fluid flow at a succession of ranges along the beam path; and

means for comparing said representation with predetermined data to obtain a representation of the cross-sectional area of the conduit.

10 10. Apparatus according to Claim 9 in which a single transducer operates as both transmitter and receiver, the transducer being operated in a pulsed manner.

11. Apparatus according to Claim 9 or 10 in which said signal processing means comprise:

15 means for providing a signal representing only Doppler components of the returning signals which are associated with the movement of fluid within the conduit; and

means for time-gating the signal provided to produce a set of Doppler power representations from successive ranges along the beam path.

20 12. Apparatus according to Claim 11 in which the Doppler signal is multigated to provide simultaneous signals from the plurality of ranges along the beam path.

13. Apparatus according to any one of Claims 9 to 12 in which the transducer producing the divergent ultrasound beam comprises a piezoelectric element within a cylindrical housing, the element being mounted adjacent to an aperture in an end wall of the housing.

25 14. Apparatus according to any one of Claims 9 to 12 in which the transducer producing the divergent ultrasound beam comprises a central element and a surrounding substantially concentric annular element, the two elements being driven in antiphase.

1/2

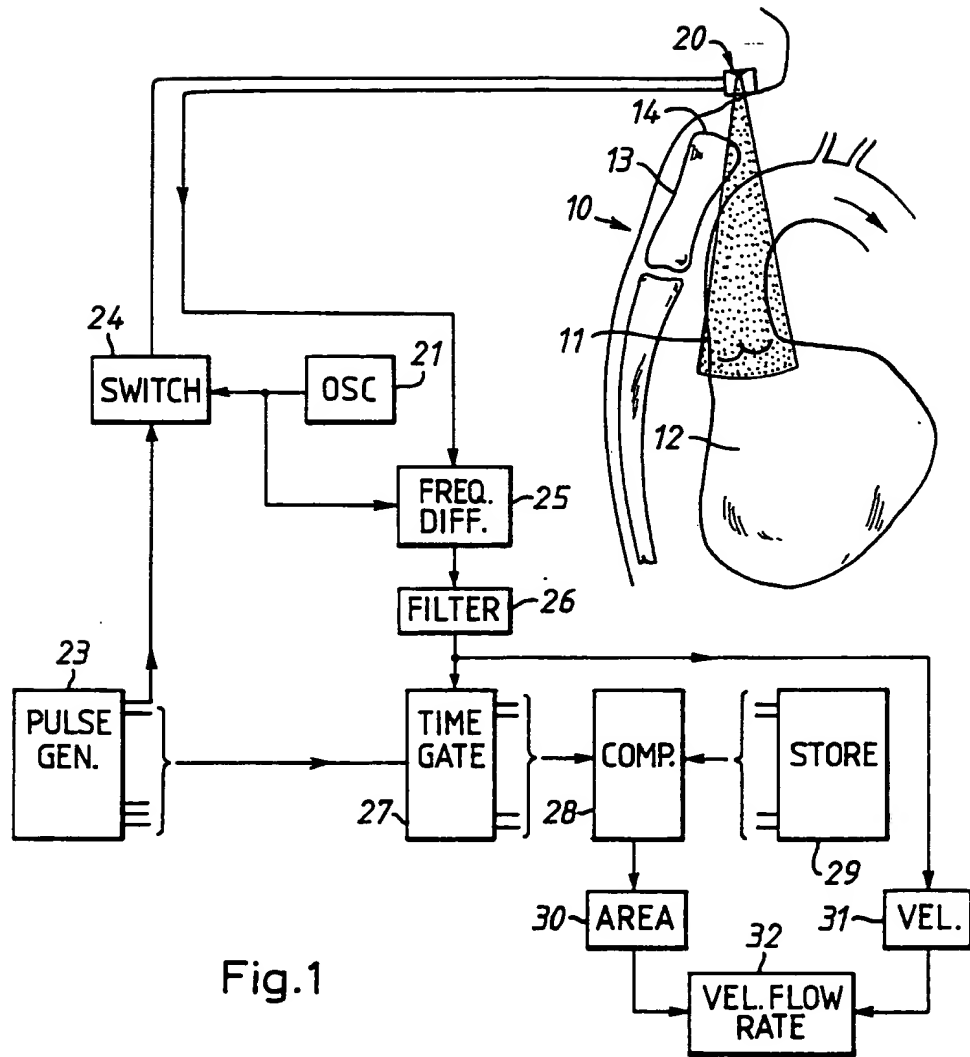


Fig.1

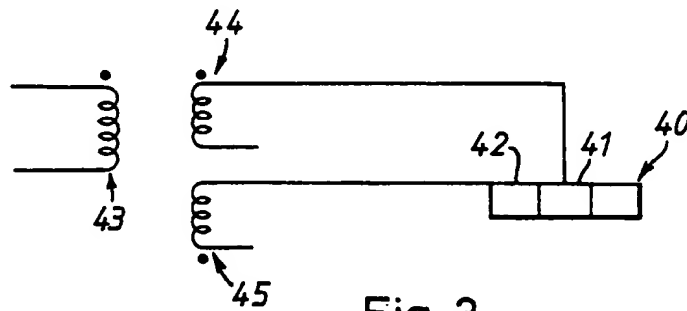


Fig. 3

2/2

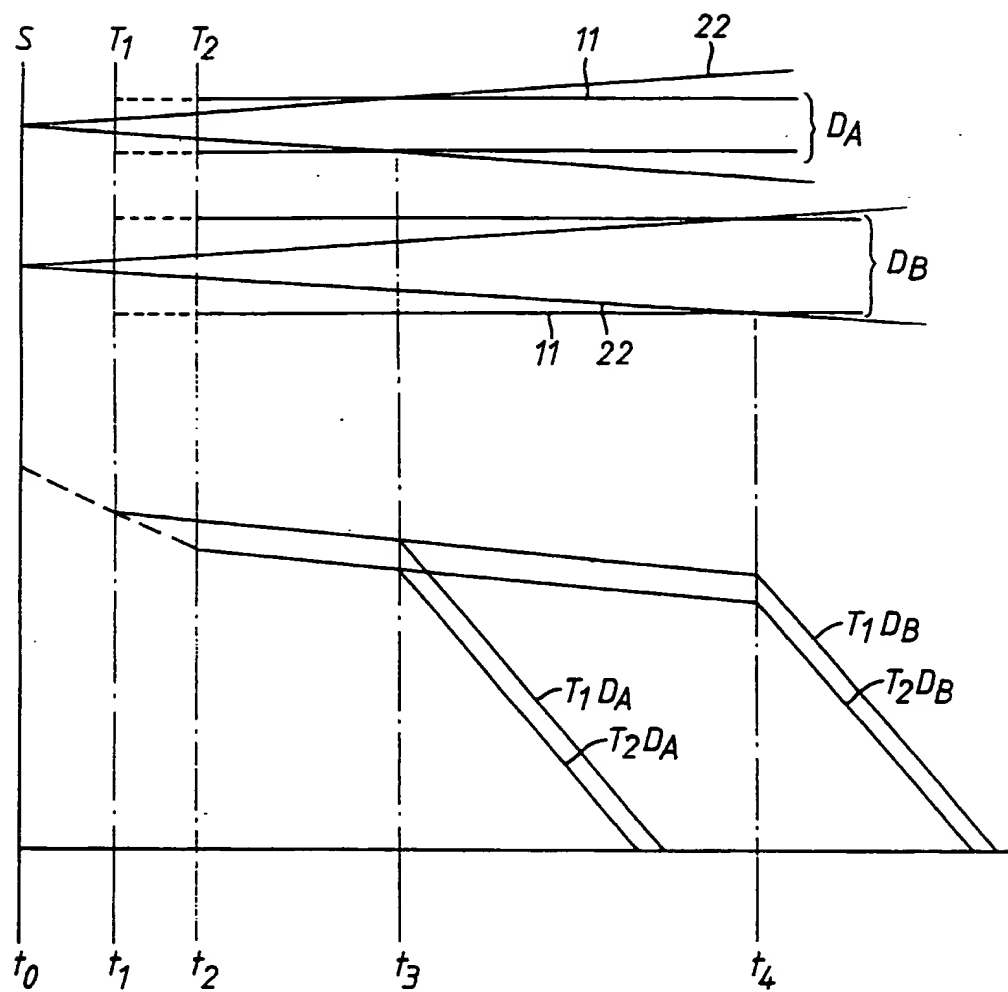


Fig. 2

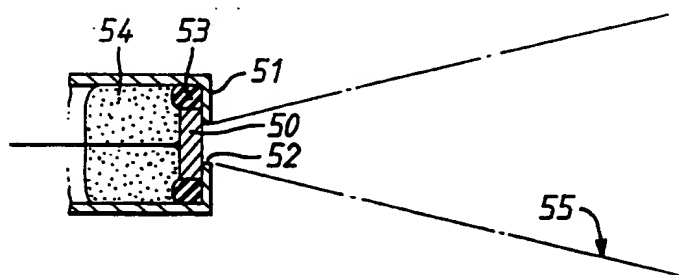


Fig. 4

## INTERNATIONAL SEARCH REPORT

PCT/GB 92/01061

International Application No.

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B8/08; A61B8/06; G01B17/00		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
Int.Cl. 5	A61B ; G01B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	WO,A,8 904 634 (WATERS INSTRUMENTS INC.) 1 June 1989 see the whole document	1-4,6-13
A	EP,A,0 035 325 (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 9 September 1981 see the whole document	1-3
A	US,A,4 757 822 (C. DI GIULIOMARIA ET AL.) 19 July 1988 see the whole document	1-3
-/--		
<p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
31 AUGUST 1992	22. 09.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	HUNT B.W.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	<p>IEEE TRANSACTIONS ON ULTRASONICS, FERROELECTRICS AND FREQUENCY CONTROL vol. 37, no. 3, May 1990, NEW YORK US pages 176 - 189; P.M.EMBREE ET AL.: 'Volumetric Blood Flow via Time-Domain Correlation: Experimental Verification' Paragraph: "IV. VOLUMETRIC FLOW MEASUREMENT METHOD" see page 181 - page 185</p> <p>---</p>	1-3
A	<p>US,A,4 476 874 (J.C.TAENZER ET AL.) 16 October 1984 see column 15, line 11 - column 17, line 39; figures 5-7</p> <p>---</p>	1,9
A	<p>WO,A,8 303 000 (THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY) 1 September 1983 see page 9, line 7 - line 18; figures 1-10</p> <p>---</p>	9,14

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO. GB 9201061  
SA 60671**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 31/08/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-8904634	01-06-89	EP-A- 0386130	12-09-90
		JP-T- 3501933	09-05-91
		US-A- 5052395	01-10-91
-----			
EP-A-0035325	09-09-81	GB-A,B 2070771	09-09-81
		JP-A- 56137113	26-10-81
		US-A- 4391148	05-07-83
-----			
US-A-4757822	19-07-88	None	
-----			
US-A-4476874	16-10-84	None	
-----			
WO-A-8303000	01-09-83	US-A- 4431936	14-02-84
		EP-A,B 0101509	29-02-84
		EP-A- 0316511	24-05-89
		JP-T- 59500332	01-03-84
		US-A- 4519260	28-05-85
-----			

EPO FORM P0479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82